

The Role of Privacy Law in Genetic Research

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Abstract: Rapid advances in genetic research have resulted in the mass production of genetic data as well as the emergence of public and private genetic databases that disseminate this data to the public. The increase in access to genetic information has resulted in advanced understanding of disease epidemiology and treatment; however, it also presents a new threat to the genetic privacy of individuals. This paper discusses the current federal and state regulations that control disclosure of genetic information for research purposes. Specifically, HIPAA and the federal Common Rule are analyzed as well as their impact on genetic research. In addition, this paper discusses the emergence of biobanks and the lack of federal regulation addressing them. Lastly, this paper examines the tension between stricter privacy regulations specific to genetic research and the advancement of science.

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I. INTRODUCTION

Rapid advances in scientific research have spawned a new threat to privacy. Technological innovations provide researchers with the means to sequence entire genomes and publicly disseminate the data through private and public genetic databases. These technological advances pose a threat to the privacy of genetic information for individuals who either directly or indirectly participate in genetic research, raising a number of ethical issues that federal legislation has failed to address.

Current federal legislation, which consists of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the federal Common Rule, fails to address the ethical concerns of genetic privacy. The federal legislation is limited in its scope, allowing a large number of researchers to evade both laws and further compromise the privacy of an individual's genetic information. HIPAA demands compliance only from institutions that are covered entities and that participate in activities involving "protected health information" ("PHI"). Similarly, the federal Common Rule is only applicable to institutions that receive federal funding from an agency regulated by the Common Rule, leaving a large portion of the private sector free from regulation.

The lack of a comprehensive federal scheme for protecting genetic information has prompted a number of states to implement state laws that aggressively address the ethical concerns of genetic privacy.¹ A number of these state laws distinguish genetic information from other health information, making genetic information subject to stricter guidelines than those imposed on general medical information.

This paper first provides a comprehensive overview of federal legislation, focusing on HIPAA and the Common Rule, the two major regulatory schemes that address the privacy of genetic material. Further, this paper discusses how both HIPAA and the Common Rule grant genetic information only limited protection because research institutions can avoid compliance by classifying themselves as non-covered entities or by rejecting federal funding from any agency regulated by the Common Rule. The federal government has failed to implement legislation that specifically addresses genetic privacy, thereby affording genetic information protection only if it is identified

¹ See Nat'l Cancer Inst., 50-State Survey of Human Tissue Regulation, http://www.cancerdiagnosis.nci.nih.gov/specimens/50_state_survey/analysis2.htm (last visited Jan. 26, 2009) (provides analysis of current state genetic laws).

as “PHI” or the genetic research is funded by a federal agency that accepted compliance under the Common Rule.

Secondly, this paper provides a survey on state legislation that implements stricter regulations regarding genetic material. A number of states have passed legislation specifically addressing the privacy of genetic information. In most of these states, genetic information is subject to more stringent regulation than under federal laws. Many of these state laws require researchers to obtain informed consent from research participants, allowing researchers to use genetic material only in the manner provided by the consent.

In addition to providing an overview of state and federal law, this paper addresses the impact of genetic databases on genetic privacy and proposed methods to resolve the existing tension between genetic privacy and the continuing advancement of science. The Internet has provided a means for the collection and dissemination of an enormous amount of genetic data; however, proposed federal legislation has made no attempt to regulate the privacy of this genetic information. A number of methods have been proposed to address this emerging concern, such as masking, collecting, and disseminating material only from individuals giving explicit consent, and regulating genetic material under federal legislation. The method receiving the most widespread endorsement is to bring genetic material under federal regulation, which provides privacy to individuals while still furthering scientific advancement.

II. OVERVIEW OF FEDERAL REGULATIONS FOR GENETIC RESEARCH

A. THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 AND ITS IMPACT ON RESEARCH

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) requires standardization of a patient’s electronic health, administrative and financial data.² It also provides security and privacy standards for PHI.³ PHI is “individually identifiable health information, held or maintained by a covered entity or its business associates acting for the covered entity that is transmitted or

² Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936.

³ 45 C.F.R. § 160.103 (2007); 45 C.F.R. § 164.502 (2001).

maintained in any form or medium.”⁴ Health information includes any information, whether oral or recorded in any form, that “relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for health care to an individual.”⁵

1. HIPAA’S IMPACT ON MEDICAL AND SCIENTIFIC RESEARCH

Medical and scientific research is most directly affected by the Privacy Rule implemented by HIPAA. The section of HIPAA relating to medical and scientific research “establishes conditions under which PHI can be used within an institution and disclosed to others outside it; grants individuals rights regarding their PHI; and requires that institutions maintain the privacy and security of PHI.”⁶ Compliance with HIPAA guidelines is only mandated when the information utilized in research is identifiable PHI. PHI is identifiable if it includes one or more identifiers, such as a patient’s name, a geographic subdivision smaller than a state, dates associated with a patient or other identifying numbers.⁷

In general, the HIPAA Privacy Rule allows for a covered entity⁸ to use and disclose PHI for research if it is authorized to do so by the research subject in accordance with the guidelines outlined in the Rule.⁹ For example, a valid HIPAA Privacy Rule authorization can include a signed statement by the research subject that grants permission to a covered entity to disclose PHI to a specified

⁴ 45 C.F.R. § 160.103; *see also* Dep’t of Health & Hum. Servs., *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule*, http://privacyruleandresearch.nih.gov/pr_02.asp (last visited Jan. 26, 2009).

⁵ 45 C.F.R. § 160.103.

⁶ 45 C.F.R. § 160 (2007); 45 C.F.R. § 164 (2007); *see also* YALE UNIV. SCH. OF MED., YALE UNIVERSITY RESEARCHERS’ GUIDE TO HIPAA PRIVACY: HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 HANDBOOK, <http://www.med.yale.edu/hic/hipaa/guide/index.html#hipaa> (last visited Jan. 26, 2009).

⁷ YALE UNIV. SCH. OF MED., *supra* note 6; *see also* 45 C.F.R. § 164.502.

⁸ The covered entities to which HIPAA are applicable are health plans, health care clearinghouses, and health care providers that routinely handle protected health information. 45 C.F.R. § 164.103.

⁹ *Id.*

recipient.¹⁰ An authorization obtained for research purposes must specifically state the research study that the PHI will be used for and cannot authorize use of the PHI for non-specific or future research.¹¹ When the covered entity, pursuant to an authorization, discloses PHI to another covered entity, the Privacy Rule continues to apply. However, if the recipient is a non-covered entity, the Privacy Rule does not protect the PHI once disclosed.¹²

Alternatively, disclosure of PHI for research purposes by a covered entity can occur without authorization if there is a waiver of authorization. This can happen if the disclosure is approved by an institutional review board (“IRB”) protocol; if there is a limited data set that is subject to a data use agreement; if the information is used in preparatory research; or if the data is deidentified.¹³

A researcher can make a request to an institution’s IRB to have authorization waived even when the research involves PHI. A waiver of authorization is available only in a limited number of circumstances, such as when research cannot be practicably conducted without the waiver or without access to the PHI. In order to receive a waiver of authorization:

The researcher must provide written assurance to the IRB that the PHI will not be re-used or disclosed, that the use(s) and/or disclosure(s) of the PHI will be limited to the minimum necessary standard, and that the use(s) and/or disclosure(s) involve no more than minimal privacy risk to the subjects.¹⁴

Researchers can also utilize PHI without authorization when the research uses a limited data set or is used in preparatory research.¹⁵ A

¹⁰ 45 C.F.R. § 164.508 (2007).

¹¹ *Id.*

¹² *Id.*

¹³ 45 C.F.R. § 164.512 (2007); 45 C.F.R. § 164.514 (2007). “Deidentified protected health information includes health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual.” 45 C.F.R. § 164.514 (2007).

¹⁴ 45 C.F.R. § 164.512; *see also* YALE UNIV. SCH. OF MED., *supra* note 6.

¹⁵ 45 C.F.R. § 164.514.

limited data set contains a small number of identifiers and presents only a minimal potential of identifying the individual with whom the identifiers are associated.¹⁶ The use of limited data sets is restricted to research and to public health or health care operations.¹⁷ Preparatory research access “is limited to a review of data to assist in formulating a hypothesis, determining the feasibility of conducting the study, determining cell size, or other similar uses that precede the development of an actual protocol.”¹⁸

Academic institutions can completely exempt research sectors of a university from HIPAA regulation by electing to classify the university as a “hybrid entity.”¹⁹ A university may qualify as a hybrid entity when a single entity performs activities that include both covered and uncovered functions.²⁰ The university must designate the areas of the institution that conduct electronic transactions of PHI as covered entities.²¹ All other areas that are not involved in the transaction of PHI will be identified as non-covered entities. The covered entities (most often university hospitals) must comply with the Privacy Rule, whereas the non-covered entities (most often research laboratories) do not.

2. HIPAA’S LIMITED IMPACT ON GENETIC INFORMATION

Genetic information has become one of the greatest research tools available in determining disease epidemiology and promoting treatment. Genetic information used daily in scientific research contains intimate and personal information, which raises major privacy concerns. The federal government, however, has failed to address or provide special privacy protection for genetic information in the context of genetic research.²²

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ 45 C.F.R. § 164.512; *see also* YALE UNIV. SCH. OF MED., *supra* note 6.

¹⁹ 45 C.F.R. § 164.103 (2007); 45 C.F.R. §164.105 (2007).

²⁰ 45 C.F.R. § 164.103.

²¹ 45 C.F.R. § 164.105.

²² *See, e.g.*, Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (prohibits U.S. insurance companies and employers from discriminating on the basis of information derived from genetic tests).

Only covered health care entities that deal with genetic information are required to comply with the HIPAA regulations.²³ These covered entities include providers of general medical services that create or receive genetic information, as well as individuals that provide genetics services, including the administration and interpretation of genetic tests. This may mean that genetic information generated and compiled in a research setting will be excluded from HIPAA regulations because the researchers that generate the genetic information are not covered entities. Under the current version of HIPAA, genetic information used in research is only protected if the researcher is characterized as a covered health care provider or employed by an institution that is regulated by the HIPAA provisions.

If genetic information falls within the scope of current HIPAA privacy regulation, it will be afforded the same protection as other health care information under HIPAA; thus, it can be disclosed for treatment, payment, and other health care operations only after the patient gives written consent of such disclosure.²⁴

B. THE FEDERAL COMMON RULE AND ITS APPLICABILITY TO HUMAN RESEARCH

The Common Rule is a federal policy regarding the protection of human subjects, and it applies to research funded by a number of federal agencies.²⁵ It requires an IRB to review proposed research, the researcher to obtain informed consent from the research subject, and assurance by the research institution that it will comply with the Common Rule regulations.²⁶ HIPAA's requirements pertaining to research do not replace or override the requirements of the federal Common Rule.

The Common Rule only applies to research conducted or funded by the federal agencies that have adopted it.²⁷ Therefore, research funded by a participating federal agency must comply with the

²³ See 45 C.F.R. § 160; 45 C.F.R. § 164.

²⁴ 45 C.F.R. § 164.502 (2007).

²⁵ 45 C.F.R. § 46.101 (2007).

²⁶ 45 C.F.R. § 46.103 (2007); 45 C.F.R. § 46.116 (2007).

²⁷ 45 C.F.R. § 46.101 (2007).

regulations outlined in the Common Rule. Alternatively, federal law does not demand compliance with the Common Rule when research is conducted independent of federal funding from an agency that has adopted the Common Rule.²⁸

Researchers that receive funding from one of the federal agencies that adopted the Common Rule must seek the approval of an IRB before engaging in research with human subjects.²⁹ A “human subject” “includes human blood or tissue samples, as well as archival medical information associated with the samples if the samples or information, either directly or via coded identifiers, are linked to individual donors.”³⁰

In regard to collecting genetic information, institutions receiving federal funding must abide by the Common Rule provisions because genetic information is isolated from blood and tissue samples, both of which are considered part of a “human subject” under the Common Rule provisions. When research involves genetic testing, the federal Office of Human Research Protections (“OHRP”) recommends that IRBs require investigators to inform subjects of potential risks, including psychosocial risks that may arise from any breach of confidentiality associated with the research.³¹

The Common Rule uses IRB review as the primary mechanism for protecting human subjects and ensuring that adequate informed consent is obtained prior to the start of a research project. Under the Common Rule, all protocols involving human subjects must first be approved by an institution’s IRB.³² An IRB is not an accredited entity, but it is required to meet certain membership requirements and follow specified review procedures outlined in the Common Rule.³³

Meaningful informed consent is fundamental to ensuring protection of human research subjects. The Common Rule works to ensure that meaningful informed consent is obtained by specifying how informed consent should be documented, rather than focusing on

²⁸ 45 C.F.R. § 46.102 (2007).

²⁹ 45 C.F.R. § 46.101 (2007).

³⁰ 45 C.F.R. § 46.102 (2001).

³¹ See DEP’T OF HEALTH & HUM. SERVS., INST. REVIEW BD. GUIDEBOOK, CHAPTER V, SEC. H (1993), http://www.hhs.gov/ohrp/irb/irb_chapter5ii.htm.

³² 45 C.F.R. § 46.109 (2007).

³³ 45 C.F.R. §§ 46.107–46.109.

the process used to obtain it. To comply with the Common Rule, a researcher needs to obtain informed consent (usually in writing) from a research subject (or that subject's authorized representative) prior to enrolling the subject in the research study.³⁴

C. DISTINCTIONS BETWEEN THE PRIVACY RULE AND THE COMMON RULE

The requirements of the HIPAA Privacy Rule are somewhat different than the Common Rule in that HIPAA requires patient authorization to release PHI (authorization is one of the four paths to pursue research under HIPAA),³⁵ whereas the Common Rule requires informed consent prior to participation in research. Further, the applicability of the two federal laws varies. The Privacy Rule requires authorization for release of PHI for postmortem research,³⁶ while the Common Rule applies only to living individuals.³⁷ Because the Common Rule and the Privacy Rule have different requirements for what information must be "protected," researchers may have to meet requirements of HIPAA, the Common Rule, both or none at all.

III. STATE LAWS IMPOSE HIGHER STANDARDS TO PROTECT PRIVACY OF GENETIC INFORMATION

The lack of federal legislation regarding genetic information prompted numerous states to pass laws that impose higher standards for protection of genetic information. To date, twenty-nine states have passed legislation that place restrictions on genetic tests and the collection and disclosure of genetic information.³⁸ These restrictions have varying effects on genetic research, which depend upon the definitions of "genetic information" and "genetic tests" and how broadly these terms are defined in the legislation. The most restrictive

³⁴ 45 C.F.R. § 46.116.

³⁵ For a discussion of alternate paths, see *infra* Section IV.A.

³⁶ 45 C.F.R. § 164.502 (2007).

³⁷ 45 C.F.R. §§ 46.101–102 (2007).

³⁸ See NAT'L CONF. OF STATE LEGISLATURES, STATE GENETIC PRIVACY LAWS, <http://www.ncsl.org/programs/health/genetics/prt.htm> (last visited Jan. 26, 2009) (provides a list of state's genetic laws); see also Nat'l Cancer Inst., *supra* note 1.

effect of these laws on research occurs when genetic testing is defined so broadly as to include the most basic components of DNA.³⁹

Among the states that have passed legislation regulating genetic information, twenty-one states allow researchers to use genetic information when specific conditions are met, with the most common condition being protection of the patient's identity.⁴⁰ This approach differentiates between the use of tissue and data in the clinical setting from use in the research setting, imposing less restrictive measures on research activities.

Both Massachusetts and Nebraska laws use language that exclude or limit the restrictions on the use of genetic information used for research.⁴¹ For example, Massachusetts's statute describes genetic information that is excluded from the restrictions implemented by the statute, as information that is gathered from a clinical or diagnostic test of DNA, RNA, or other genetic components: "The term genetic information shall not include any information about an identifiable person that is taken: (1) as a biopsy, autopsy, or clinical specimen solely for the purpose of conducting an immediate clinical or diagnostic test that is not a test of DNA, RNA, mitochondrial DNA, chromosomes or proteins."⁴²

Similarly, Nebraska's law excludes from the definition of genetic test any activity conducted in accordance with biomedical research.⁴³ Alternatively, Louisiana, New Hampshire, New Mexico, Oregon and Iowa use broad language that includes research within the scope of the statutes' definition of "genetic test."⁴⁴ Within these states, the use of tissue samples, including those used in genetic research, is governed by the restrictions set out in the states' laws.⁴⁵

³⁹ LA. REV. STAT. ANN. § 22: 213.7 (2007).

⁴⁰ See NAT'L CONF. OF STATE LEGISLATURES, *supra* note 38; see also Nat'l Cancer Inst., *supra* note 1.

⁴¹ MASS. GEN. LAWS ANN. ch. 111, § 70G (West 2000); NEB. REV. STAT. § 77-5519 (2007).

⁴² MASS. GEN. LAWS ANN. ch. 111, § 70G; see also Nat'l Cancer Inst., *supra* note 1.

⁴³ NEB. REV. STAT. § 77-5519 (2005).

⁴⁴ LA. REV. STAT. ANN. § 22:213.7 (2008); N.H. REV. STAT. ANN. § 141-H:1 (2007); N.M. STAT. ANN. § 24-21-2 (West 2005); OR. REV. STAT. §§ 192.531-192.549 (2007); IOWA CODE §729.6 (2007).

⁴⁵ See statutes, *supra* note 44.

The variance in state law is not limited to the language used in the legislation but also applies to the restrictions that are imposed by each state's legislation. Twenty-seven states require informed consent⁴⁶ from the individual providing the genetic material before the information and/or material can be disclosed for research purposes, with a subset of these states specifying the type of written authorization required.⁴⁷ Within a number of states requiring informed consent, specific provisions are included that regulate the retention and future use of blood and tissue samples. For instance, Michigan and Nebraska require that informed consent incorporate a statement of future use of the sample and specify who will have access to the sample.⁴⁸ New Jersey presents one of the strictest laws regarding the use of genetic samples for research purposes.⁴⁹ It requires all samples to be destroyed after completion of the research project unless individual consent is obtained to retain the sample.⁵⁰ However, most states only require informed consent for use of genetic data in research if the genetic material is identifiable and can be linked to an individual.⁵¹

⁴⁶ MICH. COMP. LAWS § 333.17520 (2008) ("Informed consent consists of a signed writing executed by the test subject or the legally authorized representative of the test subject that confirms that the physician or the individual acting under the delegatory authority of the physician has explained, and the test subject or the legally authorized representative of the test subject understands, at a minimum, all of the following: (a) The nature and purpose of the presymptomatic or predictive genetic test; (b) The effectiveness and limitations of the presymptomatic or predictive genetic test; (c) The implications of taking the presymptomatic or predictive genetic test, including, but not limited to, the medical risks and benefits; (d) The future uses of the sample taken from the test subject in order to conduct the presymptomatic or predictive genetic test and the information obtained from the presymptomatic or predictive genetic test; (e) The meaning of the presymptomatic or predictive genetic test results and the procedure for providing notice of the results to the test subject; (f) Who will have access to the sample taken from the test subject in order to conduct the presymptomatic or predictive genetic test and the information obtained from the presymptomatic or predictive genetic test, and the test subject's right to confidential treatment of the sample and the information.").

⁴⁷ See 45 C.F.R. § 164.508.

⁴⁸ MICH. COMP. LAWS § 333.17520; NEB. REV. STAT. § 71-551 (2008).

⁴⁹ N.J. STAT. ANN. § 10:5-46 (2002).

⁵⁰ *Id.*

⁵¹ ARK. CODE ANN. § 20-35-103 (2008); OKLA. STAT. tit. 36, § 3614.4 (2008).

IV. THE HEIGHTENED CONCERN OF PRIVACY PERTAINING TO GENETIC DATABASES

A. THE REASONS BEHIND THE HEIGHTENED CONCERN

Genetic databases consist of a collection of genetic and medical information from a large number of people, arranged in a systematically searchable way. Genetic databases have exploded in popularity among researchers due to advances in scientific technologies that allow for rapid sequencing of DNA at relatively little cost. DNA sequencing produces enormous amounts of data that hold great potential for use in determining disease epidemiology and therapeutic treatments. Continuing advances in computer technology mean that this abundant amount of genetic information can be stored, analyzed and disseminated for public use. While the generation of this genetic information holds great potential for treatment and diagnosis of diseases, it also carries great risk to an individual's privacy.⁵²

Under current federal legislation, DNA sequences could potentially be regulated by the Common Rule, which regulates all federally funded research and sets forth federal policy concerning the use of human subjects and HIPAA.⁵³ However, the Common Rule will not apply to DNA sequences unless the research utilizes human subjects. Human subject research is defined under the Common Rule as research involving "an individual about whom the investigator . . . obtains data through intervention or interaction with the individual, or identifiable private information."⁵⁴

According to a guidance document published in 2004 by the OHRP, data collected for a sequencing study is not subject to federal regulation because the data is collected and coded by a primary clinical investigator; the coded material is then provided to a sequencing investigator who is prohibited from deciphering the code, thus rendering the data unidentifiable.⁵⁵ Likewise, HIPAA provides

⁵² Peter Gwynne & Gary Heebner, *Advances in Genomics—Fresh Steps in Sequencing*, SCIENCE, June 10, 2005, http://www.sciencemag.org/products/gen_061005.dtl#Systems.

⁵³ 45 C.F.R. § 46.101 (2007).

⁵⁴ 45 C.F.R. § 46.102 (2007).

⁵⁵ Dep't of Health & Hum. Servs., *Guidance on Research Involving Coded Private Information or Biological Specimens*, Aug. 10, 2004, <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiolo4.htm>.

little protection of genetic information obtained through DNA sequencing due to the uncertainty of whether genomic data constitutes identifiable PHI.

B. PROPOSED RESPONSES TO PROTECTING PRIVACY OF GENETIC INFORMATION IN GENETIC DATABASES

Presently, privacy concerns about public release of genetic information have been addressed by ensuring that disclosed information is deidentified. However, the current measures may prove to be inadequate for maintaining the privacy of genetic information as databases continue to proliferate and technology continues to advance and become more sophisticated. Scientists admit that coded or deidentified sequenced DNA may be readily linked to an individual as databases continue to expand in number and sophistication.⁵⁶ For example, a study in 2004 found that an individual can be uniquely identified using a small number of genetic markers when compared to a sample reference taken from the same subject.⁵⁷ The sample reference need not be a blood sample, but can come from hair or other genetic material that may be surreptitiously obtained.

Due to the lack of federal regulation of privacy issues pertaining to genomic research, a number of alternative methods have been proposed to address the furtherance of genetic research while still maintaining an individual's right to privacy.⁵⁸ One proposed method

⁵⁶ Latanya Sweeney, *Weaving Technology and Policy Together to Maintain Confidentiality*, 25 J.L. MED. & ETHICS 98 (1997); Bradley Malin & Latanya Sweeney, *How (not) to Protect Genomic Data Privacy in a Distributed Network: Using Trail Re-identification to Evaluate and Design Anonymity Protection Systems*, 37 J. BIOMEDICAL INFO. 179 (2004); Nat'l Cancer Inst., *Confidentiality, Data Security, and Cancer Research: Perspectives from the National Cancer Institute*, Mar. 23, 1999, www3.cancer.gov/confidentiality.html.

⁵⁷ Zhen Lin, Art Owen & Russ Altman, *Genomic Research and Human Subject Privacy*, 305 SCIENCE 183 (July 9, 2004), available at <http://www.sciencemag.org/cgi/content/full/sci;305/5681/183?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=zhen+lin&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT>.

⁵⁸ See Amy L. McGuire & Richard A. Gibbs, *Genetics: No Longer De-Identified*, 312 SCIENCE 371 (Apr. 6, 2006), available at <http://www.sciencemag.org/cgi/content/full/sci;312/5772/370?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=amy+mcguire+richard+gibbs&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT>.

is to implement a data access system that masks highly sensitive data.⁵⁹ A masking data access system provides electronic methods for separating raw genetic data from personally identifiable information.⁶⁰ The system prevents access to sensitive personal information while still permitting access to the raw genetic material.

However, the data access system fails to address the tension between the progression of genetic research and privacy, in that the masking of personal data may render raw genetic material useless for research. In particular, genetic research pertaining to epidemiology requires access to information that goes beyond raw genetic material. Advances in this field require that the raw genetic material be accessed in conjunction with personal information (such as background of familial diseases or disorders) to determine the significance of a particular gene mutation and how this mutation correlates with inheritable diseases.

Another proposed method to bridge the gap between scientific progression and privacy of genetic information is to only seek out individuals who agree to have their information publicly disclosed and to provide those individuals with control over the dissemination of their information.⁶¹ This option protects an individual's privacy, but, unfortunately, threatens the progression of genetic research. With the increasing threat of genetic discrimination, individuals will likely become more concerned with dissemination of their genetic material and will be less likely to voluntarily participate in genomic research without the assurance of protection.⁶² In addition, this option may present researchers with a biased set of genetic material. The genetic information available to researchers would be only from individuals willing to voluntarily participate, which may limit data to a specific set of individuals and threaten the advancement of genetic research.⁶³

⁵⁹ *Id.*

⁶⁰ Gabrielle Kohlmeier, *The Risky Business of Lifestyle Genetic Testing: Protecting Against Harmful Disclosure of Genetic Information*, 11 UCLA J.L. & TECH. 2, 5 (2007).

⁶¹ Isaac S. Kohane & Russ B. Altman, *Health Information Altruists—A Potentially Critical Resource*, 353 NEW ENG. J. MED. 2074, 2076 (2005).

⁶² Francis S. Collins & James D. Watson, *Genetic Discrimination: Time to Act*, 302 SCIENCE 745 (Oct. 31, 2003); Mark Rothstein, *Expanding the Ethical Analysis of Biobanks*, 33 J.L. MED. & ETHICS 89 (2005).

⁶³ Collins & Watson, *supra* note 62.

A third and the most viable method to protect genetic information is to bring genomic databases under the scope of federal regulations. This can be accomplished either by identifying the research as human subject research and thereby providing protection under the Common Rule, or by providing protection to genomic data under HIPAA. To protect genomic data under HIPAA, genetic information must be specifically classified as PHI, which requires authorized consent or a waiver of consent from the individual before the genetic material can be used in research. By implementing a federal regulation that specifically defines genomic information as regulated material, it will foster public confidence in privacy; this may increase the willingness of individuals to partake in genetic research, thereby enabling scientific progress.

V. A GAP IN PRIVACY LAW: THE DANGER OF COMMERCIAL DATABASES

Recently, a number of commercial biotech companies that collect and store genetic information have emerged in the United States. These privately held companies provide a variety of private services and products including: paternity tests, genetic testing for predisposition for certain diseases and traits, genealogy and the tracing of origin, ancestry, and pharmacogenomics.⁶⁴ These companies not only provide a service to the consumer, but also provide profits to the company by compiling the consumer's sample into a "biobank" that can be accessed by researchers for a fee. The popularity of biobanks is rising due to economic incentives and the lack of federal regulation of these databases.⁶⁵

The Common Rule does not apply to the majority of biotech companies because they are privately funded and do not receive money from federal agencies. Similarly, whether HIPAA regulations apply to these companies is questionable due to the uncertainty of whether the privately held biobanks are categorized as covered

⁶⁴ Examples of commercial companies running private biobanks include Genomics Collaborative Inc., GolfStream Bioinformatics (formerly Arda's Corporation), 23andMe and DNA Sciences, Inc.

⁶⁵ See Yael Bregman-Eschet, *Genetic Databases and Biobanks: Who Controls Our Genetic Privacy?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1; Jocelyn Kaiser, *Population Databases Boom, From Iceland to the U.S.*, 298 SCIENCE 1158 (Nov. 8, 2002), available at <http://www.sciencemag.org/cgi/content/full/sci;298/5596/1158?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=kaiser+population+databases&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT>.

entities.⁶⁶ While it is clear that companies directly receiving genetic material from consumers are not covered entities, and therefore, not regulated by HIPAA, it is unclear whether companies that receive samples from medical centers (which are covered entities) are themselves covered entities under HIPAA. The privately held companies may be considered business associates of the medical center, providing limited protection to genetic material transferred between the two institutions.⁶⁷ Business associates are not directly required to comply with the Privacy Rule; instead, protection of genetic information is achieved by a contract between the business associate and the covered entity.⁶⁸ The contract should require that the genetic information remain protected after disclosure to the business associate.⁶⁹ However, if the information is deidentified by the medical center, the biotech company will not be required to comply with HIPAA even if the coding of the information is reversible.⁷⁰

If states have failed to impose additional legislation, the lack of federal regulation leaves biotech companies to self-regulate. This lack of regulation also leaves individuals vulnerable to misuse of genetic material submitted to a company for genetic testing and creates the potential for public exposure of sensitive genetic material.⁷¹ Recently, there have been state actions to limit activities of biobanks for non-privacy reasons, usually because the testing is not being done in the types of laboratories required by state law.⁷² Even if the non-privacy issues are resolved, biobanks will continue to pose a threat to individuals' privacy.

⁶⁶ PEW INTERNET & AMERICAN LIFE PROJECT, EXPOSED ONLINE: WHY THE NEW FEDERAL HEALTH PRIVACY REGULATION DOESN'T OFFER MUCH PROTECTION TO INTERNET USERS (2001), http://www.pewinternet.org/pdfs/PIP_HPP_HealthPriv_report.pdf.

⁶⁷ *Id.* at 10.

⁶⁸ *Id.* at 16.

⁶⁹ *Id.*

⁷⁰ 45 C.F.R. § 164.502 (2007).

⁷¹ Misuse of genetic information may result in release of genetic information to third parties through clinical records or disclosures that are compelled, both of which may result in genetic discrimination. See Rothstein, *supra* note 62.

⁷² Andrew Pollack, *California Licenses 2 Companies to Offer Gene Services*, N.Y. TIMES, Aug. 20, 2008, at C3, available at <http://www.nytimes.com/2008/08/20/business/20gene.html?ref=health>.

VI. DANGERS TO RESEARCH VS. THE PRIVACY OF INDIVIDUALS

Genetic research provides researchers with invaluable information that continues to foster progression in the study and treatment of diseases. For example, the Human Genome Project has identified a number of disease-causing genes, allowing for rapid diagnosis of devastating diseases.⁷³ Future research involving data compiled from the Human Genome Project will permit scientists to study the disease-associated genes and begin to develop therapies and cures for numerous diseases. However, some of these studies will require access to DNA data and to patients' corresponding medical history. Researchers need the freedom to continue the Human Genome Project and other beneficial genetic research without the hindrance of privacy regulations. The Human Genome Project is just one example of the many areas of genetic research that must be considered when implementing privacy regulations that may threaten the progress of research.

On the other hand, privacy advocates argue that genetic material holds personal information that is the pathway into an individual's past, present, and future by disclosing a person's traits, disease patterns, and family history, and therefore, should be guaranteed privacy.⁷⁴ Many fear that without adequate protection, DNA collected for genetic research will be used in a discriminatory manner.⁷⁵ For example, health insurers could use genetic information to differentiate premiums based on an individual's background.

Accordingly, while it is true that genetic information is personal and needs protection, it is unnecessary to require more stringent privacy laws for genetic information in areas where HIPAA, the Common Rule and state laws adequately apply. When tissue and genetic information are used in research regulated by state and federal legislation, the individual is required to give informed consent or authorization prior to the release of PHI for use in research. Current legislation strikes the right balance between an individual's right to

⁷³ See Nat'l Human Genome Research Inst., All About The Human Genome Project (HGP), <http://www.genome.gov/10001772> (last visited Jan. 26, 2009).

⁷⁴ GEORGE ANNAS, ET AL., THE GENETIC PRIVACY ACT AND COMMENTARY (1995), <http://www.ornl.gov/hgmis/resource/privacy/privacy1.html>; Michael M.J. Lin, *Conferring a Federal Property Right in Genetic Material: Stepping into the Future with the Genetic Privacy Act*, 22 AM. J.L. & MED. 109, 127-29 (1996).

⁷⁵ See Nat'l Human Genome Research Inst., Genetic Discrimination, <http://genome.gov/10002077> (last visited Jan. 26, 2009).

privacy and a researcher's right to advance genetic research. To disturb the current balance by enforcing stricter regulation of genetic information would hinder the ability of researchers to recruit participants for research. On the other hand, loosening restrictions on genetic research would compromise an individual's trust in the confidentiality and privacy of their genetic information, making the individual less likely to consent to the release or use of their genetic information.

Nonetheless, further legislation must address those entities that are not currently regulated by state or federal law, and are, therefore, free to disseminate genetic material without informed consent or authorization. These entities pose a significant threat to genetic privacy.

VII. CONCLUSION

Genetic privacy is an emerging ethical concern that can best be addressed by comprehensive federal legislation. Currently, federal legislation leaves gaping holes that allow a number of researchers, both in the private and public sectors, to conduct research without consent or authorization. Many states have tried to close the holes in federal legislation by imposing stricter laws for genetic privacy; however, these laws are not uniform, and individuals are still exposed to misuse of their genetic information.

Federal legislation should be amended to specifically identify genetic material as PHI, but should not impose stricter regulations for genetic material. Amending the legislation in this manner will reach a balance that protects genetic privacy while still allowing research to progress for the benefit of humanity.